Merck & Co., Inc.
U.S. Human Health
P.O. Box 1000
North Wales, PA 19454-1099

April 25, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 05N-0016
Agency Information Collection Activities; Proposed Collection; Comment Request; Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs: Study 1

Merck & Co., Inc. is a leading worldwide human health product company. Merck's corporate mission is to discover new medicines through breakthrough research and bring those medicines to people who need them. To this end, Merck spends nearly $3 billion annually on research and development. Through a combination of state-of-the-art science and clinical research, Merck's R&D pipeline has produced many of the important pharmaceutical and biological products on the market today.

As a leading human health product company, Merck endorses the dissemination of consumer-directed educational information to encourage meaningful interactions between consumers and health care professionals (HCPs) and to inform consumers and caregivers about disease and treatments. Merck creates disease awareness communications and advertisements directed to consumers, also known as Direct-to-Consumer (DTC) promotion. In addition, we have implemented many consumer-directed print and broadcast campaigns for a variety of products and diseases, such as seasonal allergy, asthma, osteoporosis, high cholesterol, HIV infection, and chemotherapy-induced nausea and vomiting. We routinely provide patient education materials to HCPs for distribution to patients. We believe that our experience in developing information resources for patients results in DTC programs that provide clear, balanced product and disease information that encourages appropriate consumers and caregivers to consult with HCPs to learn more about treatment options and to engage in beneficial health behaviors.

Hence, we welcome the opportunity to comment on the "Evaluation of Consumer-Friendly Formats for Brief Summary in Direct-to-Consumer Print Advertisements for Prescription Drugs"[1]

Introduction

DTC advertising informs consumers about potential treatments and is intended to encourage interaction between patients and HCPs. It is important for consumers to be able to read, comprehend, and utilize both the benefit and risk information presented in DTC advertisements. For this reason, Merck supports FDA's action to conduct research to determine how to optimize the content and format of risk information in print advertisements.

Merck previously commented on the draft guidance "Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements."[2] In those comments, Merck agreed with FDA's draft recommendation to use consumer-friendly language[3] in all parts of consumer-directed materials, including brief summaries accompanying DTC advertising. In fact, Merck has been at the forefront of consumer-friendly brief summaries by creating Patient Prescribing Information (PPI) for most of its DTC-promoted products. These PPIs are used to fulfill the brief summary requirement in DTC print advertising. Merck's PPIs are developed in consumer-friendly language and are formatted in an easy-to-read question and answer format to assist comprehension.

In this docket, FDA states that "... FDA has become concerned about the adequacy of the brief summary in DTC print advertisements," and has proposed research that will help the agency understand the range of consumer uses of the brief summary, and of risk information appearing on the display page of print advertisements. To address this

---

[1] 70 FR 6691, February 8, 2005.
[2] 69FR 6308, February 10, 2004
[3] Brief Summary Draft Guidance, page 1, lines 34-35.

concern, FDA proposes to conduct a program of consumer research consisting of three separate studies. The research will be conducted by the Division of Drug Marketing, Advertising, and Communications (DDMAC). The primary objective of these studies is to identify the most effective means of providing consumers, in DTC print advertisements, with comprehensible and useful information regarding the risks associated with using advertised prescription medicines.

The objectives for each of the studies, as defined by the Federal Register posting and the FDA Division of Drug Marketing Advertising and Communications, are outlined below.

Study 1: In the Federal Register posting, FDA acknowledges that consumers may use the brief summary for many purposes, thus the purpose of Study 1 is to "investigate the nature of consumer's goals when they read prescription drug print advertisements and the relative usefulness of the information topics presented."[4] This study will "...consider the full context of the 'side effect, contraindications, and effectiveness' information presented in prescription drug advertisements, in terms of what consumers are trying to learn from the entire ad, including the display (or main) page and the brief summary, and what about each is useful."[5]

This study will address the following questions: [6]

1. How do people use the brief summary?
2. What sections are most useful for consumers?

Study 2: Will assess content issues, and will address the following questions:[7]

1. What is the right type of information?

---

[4] 70FR 6692
[5] 70FR 6692
[6] Amie C. Braman, Ph.D., DDMAC/FDA, February 24, 2005, "Getting Information to Consumers: Improving the Brief Summary," presentation.
[7] Amie C. Braman, Ph.D., DDMAC/FDA, February 24, 2005, "Getting Information to Consumers: Improving the Brief Summary," presentation.

2. What is the right amount of information?
3. How should the information be framed?
4. What is the consumers' ability to comprehend and apply information to their personal situation?

Study 3: Will assess format issues, and will address the following questions: [8]

1. What is the best way to present the (ideal) content as identified from the first two studies? (Format options may include: highlights, patient package information, and/or a risk box.)

While Study 1 is intended to uncover how consumers use DTC print advertisements and the utility of the information presented, this study in large part lays the groundwork for the collection of data in Studies 2 and 3 that will inform FDA's future recommendations for DTC print advertising and the brief summary. Merck believes that for any DTC communication to be useful to consumers it must facilitate utilization of sometimes unfamiliar medical information regarding the benefits and risks of the advertised drug. In addition to writing this information in an easy-to-understand style, it is critical that the information appears in a presentational style that encourages the consumer to stop and read the advertisement, to easily navigate through both the main body of the ad and brief summary, and to find the pertinent information that is being sought. For these reasons, Merck strongly encourages FDA to ensure that all three phases of the research are completed.

Study 1 Design

As currently proposed, consumers participating in the Study 1 would be recruited into a 2 X 4 factorial design study, using a mall-intercept protocol. The design calls for a total of 432 consumers to be divided into four disease categories; those suffering from high cholesterol, obesity, asthma or allergy (36 male/36 female per condition), or who care for

[8] Amie C. Braman, Ph.D., DDMAC/FDA, February 24, 2005, "Getting Information to Consumers: Improving the Brief Summary," presentation.

someone suffering from each condition (36 male or female). Each group would then be exposed to a single print advertisement for a fictional prescription drug that treats their particular condition. Consumers would receive one of two ad treatments: a high-risk treatment, i.e. the advertised drug may cause heart damage; or a low-risk treatment, i.e. the advertised drug may cause dry mouth.

The specifics of how potential respondents will be screened and recruited for this project, and the specifics of how they will be exposed to the high or low-risk ad treatment, has not been described in detail by FDA, beyond the fact that a mall-intercept protocol will be used, and each respondent will be exposed to only one ad treatment. Based upon information available regarding the proposed design, Merck understands that respondents will be distributed in eight cells. Within each cell, two-thirds of the respondents will be diagnosed with the specified condition, and the remaining one-third will be caregivers to a family member or close friend who is diagnosed with the condition. Thus respondents will be distributed per cell as follows: 18 male diagnosed, 18 female diagnosed, and 18 caregivers (either male or female) for a total of 54 in each cell as noted in the following table:

Rx Risk Level Presented in Ad	**Medical Condition**			
	High Cholesterol	**Obesity**	**Asthma**	**Allergies**
High-Risk (Heart Damage)	54	54	54	54
Low-Risk (Dry Mouth)	54	54	54	54
Totals	108	108	108	108

N=432

RECOMMENDATIONS

Modifications to FDA's Proposed Design

As proposed, Merck believes the current research design should adequately assess differences in consumer use of risk information across specified health conditions that include symptomatic vs. asymptomatic, and life threatening vs. non-life threatening illnesses. However, other core issues that are not included in the current design may affect how consumers use risk information in print advertising, and how useful that information is to them. Use and perceived utility of risk information may vary by the severity of the side effects associated with a drug, as proposed in the Study 1 design. Similarly, use and perceived utility may also vary by the severity of the condition, which is not proposed in the current study design. For instance, a consumer with debilitating asthma may have very different uses for the brief summary than a mild asthmatic. Therefore the research results could be affected by factors not included in FDA's current study design.

Thus Merck recommends that FDA consider modifying the proposed study design to include low and high-severity groups within each condition to determine how consumers' use of risk information varies both across disease states, and according to severity. This modification should be reflected in both the sufferer and caregiver groups. Assuming a minimum cell size of 54 consumers, this modification would effectively double the sample size from 432 to 864 respondents. The larger sample would allow for analysis of results by severity of condition, and also provide for a more robust statistical analysis of results across disease states, and between groups receiving high and low risk ad treatments. In effect, the study would be expanded to a 2 X 4 X 2 factorial design. Again, within each cell, two-thirds of the respondents will be diagnosed with the specified condition, and the remaining one-third will be caregivers to a family member or close friend who is diagnosed with the condition. Thus there will still be 54 respondents per

cell as follows:

Rx Risk Level Presented in Ad	Medical Condition & Severity							
	High Cholesterol		Obesity		Asthma		Allergies	
	High	Low	High	Low	High	Low	High	Low
High-Risk (Heart Disease)	54	54	54	54	54	54	54	54
Low-Risk (Dry Mouth)	54	54	54	54	54	54	54	54
Subtotals	108	108	108	108	108	108	108	108
Totals	216		216		216		216	

N=864

Merck realizes that budgetary and other resource limitations may understandably preclude doubling of the proposed sample size for this project. Accordingly, to stay within the project parameters as currently outlined, Merck proposes a design modification that will still allow for analysis by disease and severity. This goal can be accomplished by reducing the number of conditions included in the study from four to two. In this modified design, respondents would be recruited according to whether they suffer from, or care for someone who suffers from high cholesterol (asymptomatic condition) or asthma (symptomatic condition). The level of severity might be determined as follows:

High Cholesterol (mg/dL):

Low Severity: Respondent uses a prescription drug to lower cholesterol and his/her physician says the total cholesterol/LDL cholesterol is at an acceptable level

High Severity: Respondent uses a prescription drug to lower cholesterol and his/her physician says the total cholesterol/LDL cholesterol is still too high

Asthma:

Low Severity: Respondent uses a prescription drug to control his or her asthma, and uses a rescue inhaler twice per week or less often

High Severity: Respondent uses a prescription drug to control his or her asthma, and uses a rescue inhaler three or more times per week

This modification results in a 2 X 2 X 2 factorial design, with a total sample of 432 respondents and the same split in each cell between respondents who are diagnosed (2/3) and who are caregivers (1/3). The difference is that respondents would be distributed into only two disease states in the following manner:

Rx Risk Level Presented in Ad	**Medical Condition & Severity**			
	High Cholesterol		**Asthma**	
	High	**Low**	**High**	**Low**
High-Risk (Heart Disease)	54	54	54	54
Low-Risk (Dry Mouth)	54	54	54	54
Subtotal	108	108	108	108
Totals	216		216	

N=432

Although this proposed modification excludes obesity and allergy from the analysis, the remaining conditions, high cholesterol and asthma, have a high incidence in the population, and prescription treatments for these conditions are widely advertised. Moreover, the larger sub-samples (n=216 per condition) enhance the ability to analyze how consumers use risk information at the disease level, and to make comparisons across disease states. This modification is based on Merck's belief that differences in use of risk information likely differ more by whether a condition is symptomatic vs. asymptomatic, and by whether it is high vs. low severity than it would by the four disease states in FDA's current design. Accordingly, this modification enhances FDA's ability to analyze results across common, heavily advertised conditions, and by the added dimension of disease severity. Moreover, since the total sample size remains at 432, the modification allows for these analyses without increasing the burden on budget, resources, or respondents.

Recruiting Qualified Respondents

FDA's proposal states that respondents for Study 1 will be recruited using a mall-intercept protocol. The specifics of the protocol for Study 1 and an example of the screening questions that would identify qualified respondents are not included in FDA's request for comments for this project. Since there are several mall-intercept procedures used in market research today, Merck assumes that DDMAC plans to utilize the common method of recruiting (intercepting) potential respondents from among consumers present at a mall or public area. The interview is then completed either on the spot or at a research facility located within the mall.

Merck recommends that the FDA consider using a random-digit-dial telephone methodology (RDD) to recruit potential respondents. This approach will improve the quality of the resulting sample by increasing the likelihood that the demographic profile of the sample accurately reflects the demographics of the population under study. Moreover, the likelihood of finding a qualified respondent increases when using a telephone methodology. If the informant (the person answering the phone) is not qualified for the

study, he or she may identify another adult in the household, who can be screened and recruited for participation in the study.

Merck also recommends blinded recruitment so that respondents do not know the exact reason they qualified for the study, the nature of the interview, or the purpose of the research. Selecting respondents in this manner helps reduce the likelihood that they might prepare for the interview, or that they will be predisposed by the selection process to attend to certain types of information (such as the risk information), or respond to questions in any particular way (overstate their use of different informational elements).

Research Tool

The manner in which test advertisements are presented to consumers may affect how they react to the ads and to the high and low-risk treatments. Accordingly, Merck believes exposure to the test treatments should – as much as possible – approximate the way consumers normally see print advertisements. For example, simply handing respondents a copy of an advertisement would force them to read an ad they might not ordinarily consider and would increase their level of attention to the ad generally, and to specific content, including the risk information. The research would then overestimate attention and use of information that consumers would demonstrate in more natural settings, and thus potentially overvalue the usefulness of that information.

To mitigate these problems, Merck recommends that test advertisements be incorporated into a mock up of a regular consumer magazine (e.g. a news weekly, or a consumer health magazine), and appear with other advertising for non-drug products such as food, automobiles, or other commonly advertised products. Respondents would be asked to go through the magazine as they normally would. Interviewers would observe respondents' reading behaviors, noting whether they stopped to review the test advertisement for the drug that treats their condition. Interviewers also could note how long the respondent paused at the ad, and whether, without prompting, they checked the brief summary

information. After these information-seeking behaviors are observed, the interviewers would proceed with the interview as proposed.

Stimulus

Merck understands that one creative presentation will be used for the main body of the ad for all test cells. The body copy will be modified for the respective indication and side effect profile for each cell. Similarly, the brief summary format and presentational style will be similar for all cells. The brief summary content will be modified according to the study design for each cell.

Inherent in Merck's earlier recommendation to utilize a consumer magazine format is the need to ensure that the ad is not conspicuous in its appearance with respect to the other ads that will be included. Thus Merck suggests that, if FDA has not already done so, a consultation with a creative agency specializing in prescription drug promotion will maximize the visual interest of the ad while blending with the surrounding editorial and advertising content.

Comments Regarding the Main Body of the Ad

In addition to the above recommendation regarding creative execution, Merck recommends reconsideration of presenting a drug with a patch delivery mechanism. Merck is concerned that this less common mode of administration might distort respondents' reactions to the advertising. Since tablets are the most commonly prescribed form of prescription medicine and most people have experience taking a tablet, Merck recommends that the form for Oncor also be a tablet. This approach will avoid spending research time discussing the novel drug delivery system and allow the research to focus more clearly on its stated objective.

Also, assuming that the stimulus will be revised following the comment period, Merck suggests that FDA assure that the main body of the ad is reflective of current DDMAC

standards for DTC print advertising, including the avoidance of overly broad promotional claims and assuring reasonably comparable prominence of risk information. While this step may not significantly affect the outcome of Study 1, it is of note that the manner in which risk or benefit information is presented can affect the comprehension and retention of the information. Furthermore, the goal of Study 3 is to assess format. Paying particular attention to formatting in Study 1 could result in useful data to inform the design of the stimuli in Study 2 and, ultimately, Study 3.

Brief Summary

There are a number of sections in the brief summary stimulus that are not required by the Code of Federal Regulations: clinical trial information, dosing, ingredients, storage, how supplied, abuse potential, mechanism of action, lifestyle factors, disposal information, and cost information. Inclusion of some of these sections such as lifestyle factors and clinical trial information may provide very useful information to the reader but may distract from the desired focus on the risk information. Merck suggests that inclusion of information outside the scope of the regulations be considered carefully. In this regard, Merck believes that there is much information, beyond risk information, that may have utility for the consumer but FDA must weigh the benefit of testing for that information against focusing on the most important information that a consumer needs in order to have a more informed discussion with his/her HCP. With this as a consideration, specific comments on several sections follow.

Clinical trial information – While clinical trial information can be interesting to a wide variety of audiences, Merck believes that inclusion of clinical trial information in the brief summary stimulus may redirect the focus from other non-required but more useful information such as dosing or storage. Merck recommends removing this section.

Abuse potential – It appears that Oncor has no potential for addiction; therefore potential for abuse would not be listed as a contraindication, warning or precaution

and should be removed from the brief summary. If the risk profile for the high severity category in the study design does include potential for addiction as a warning or precaution then, under the regulations, it should be included in that section of the brief summary.

How supplied – Prescription medications are supplied in a variety of package types and sizes and the quantity of medication a consumer receives with each prescription is determined by the prescribing HCP and dispensing pharmacist. Merck recommends that this section be deleted.

How to dispose of Oncor – Because Merck recommends that FDA consider changing the form of Oncor, this section is not needed.

Cost information – While providing cost information may be very useful to consumers, cost is dependent on many factors, for example, prescription plan or, if cash-paying, pharmacy pricing. This information would not be useful and may be confusing to the many patients who have out-of-pocket co-pays for prescriptions. Merck interprets "healthcare providers," as mentioned in this section, to be the prescriber. Merck believes prescribers simply cannot be expected to know the pricing for every prescription drug for each patient's particular situation. Merck recommends that this section be deleted or revised to a simple statement directing the consumer to contact their pharmacy for exact pricing.

"What Oncor has NOT been shown to Do" – It appears this section was created specifically for the obesity test segment. Merck recommends deletion of this section. If diet and exercise are necessary precursors to prescribing Oncor, Merck assumes it would be stated in the indication and therefore should be stated as part of the "Oncor is:" section.

Draft Interview

Merck has reviewed the draft interview questionnaire for Study 1 which was provided as an attachment to the February 8, 2005 Federal Register posting. Comments to specific sections/questions in the questionnaire are provided in Appendix I.

Recap of Recommended Modifications/Suggestions

- Modify the proposed 2 X 4 factorial design to include two health conditions: high cholesterol and asthma.
- Sample 432 consumers, divided into eight groups:
  - high cholesterol or asthma
  - by high or low-severity
  - for high or low risk information
- Screen and recruit respondents through a telephone survey using a random digit dial sample. Recruitment should be blinded.
- Modify repondents' initial exposure to test advertisements by binding the ad, along with several others for both drug and non-drug products, into a typical consumer magazine (e.g. newsweekly or health magazine).
- Consult with an advertising agency that specializes in prescription drug promotion.
- Consider changing the form of the drug in the stimulus from a patch to a tablet.
- Consider deletion/modification of sections mentioned in the Brief Summary discussion, above.

In closing, Merck appreciates the opportunity to comment on the proposed study design, stimulus, and interview tool. This significant research will help the FDA make key decisions regarding DTC print advertising guidance. Merck shares the FDA's objectives

regarding this important initiative and will look forward to providing additional comments regarding this and other studies proposed by the FDA.

Sincerely,

Diana M. Scott
Vice President
Marketing Services

Enclosure

Appendix I

Comments to Selected Questions in the Interview Tool

Question	Comment
Section I Intro:	Merck suggests deleting the word "new" in the introductory comments. A consumer may read the ad for any number of reasons. Motivation and interest (reasons for reading an ad) may vary for a new drug vs. a drug a consumer is currently taking vs. a drug they have recently stopped taking. They also might have an increased interest in benefits/efficacy information vs. risk information for new drugs. This issue is important because the stated objective of the first study is to learn how or why respondents read ads, and then, based on those motivations, what specific information they seek. Merck suggests changing the wording of the second statement in this paragraph to: "*Read as you normally would if you saw an advertisement for a medicine you are already taking, or that you might be interested in for yourself or someone in your family.*" Also, consider how the interviewer will measure the time a respondent takes to read each page if the respondent flips back and forth between the display page and the brief summary.
Q. 2a-b	Assuming both of these questions are necessary, Merck recommends linking 2a with a skip pattern to 2b. If a respondent reads the entire ad, the wording of 2b can remain the same. However, if a respondent reads "very little" to "most" of the first page, then 2b should read: *"Thinking about the parts of the ad you read, did you read that information pretty thoroughly, look for certain key points, or did you just skim through those parts of the ad?"* Also, if a respondent looked for key information, Merck recommends the key information they were seeking be collected.
Q. 2c-d	Same comments as for 2a-b.
Q.3a	As currently written, Merck suggests that this question may not obtain information that meets FDA's stated objective of understanding consumers' goals for reading an ad, i.e. of learning why they read it. This question may be too general as currently written. A respondent might be reasonably expected to give unrelated answers such as: they

were thinking about the rest of their shopping, or how long the interview might last.

The question may be more effective if it asks respondents whether they noticed anything in the ad that was important to them, or asked what they typically look for, if anything, when they see this type of ad.

Q.3b-c

This question may need specific probes in order to increase the likelihood of obtaining information in line with stated objectives. For example, the following probes are suggested:

"Were you looking for specific information?"

"Did you have specific questions in mind when you read the ad?"

Respondents then might also be probed for specific categories of response, such as for specific information about product indication, side effects, contraindications, benefits, or information about comparative therapies.

Merck recommends that respondents who do no have a response to 3b should not be terminated. They should be terminated only if they have nothing to say in Q. 4a.

Q. 4a

Merck notes that the results from items i and ii may be similar to results from items vi and vii. Item i could be written more specifically to ask for product indication, e.g. trying to understand what condition Oncor treats. Item ii may not be necessary in addition to items vi and vii.

Item ix may require a follow-up, e.g. "What questions where you thinking about asking your doctor?" This question could be asked either as an open-ended query, or prompted, e.g. "Were you thinking about asking your doctor questions about the benefits, risks, or some other aspect of the drug?"

Items xiii and xiv can be removed because they do not inform the analysis.

Q. 5a-b

As written, Merck believes these questions do not differentiate between information that would be useful, if presented properly, and information that is useful the way it is currently presented. The questions also do not provide an opportunity for respondents to say

whether or not they are interested in specific topics. Consumers may be interested in a topic but the information presented may not be useful.

Merck suggests the questions could be restructured so that respondents are asked to rate their level of interest in each topic section of the brief summary or rate the importance of the information. (e.g. "How important is this information to you, personally, when you're trying to treat your _____ ?"). Then ask respondents how "useful" the information is on each topic, *as it is presented in the ad.*

In this way, FDA will obtain both an assessment of consumer importance/interest in each topic, and an assessment of its utility based on presentation.

Q. 5c

Merck suggests these questions may require specific probes that ask respondents if they still have questions about the advertised drug, and to list the questions.

5c.ii. could be reworded to ask if the page is understandable overall, which parts are not understandable, and if the page includes information that is not needed or not useful

This series might also include a question about overall clarity,

- *"Is there any information in the ad that is confusing?"*
- *"What specific parts (topics) confused you?"*
- *"Do you have a suggestion for making the information clearer under that specific topic heading?"*

Q. 6

Merck suggests the phrase "helps me understand," may be difficult to interpret in the analysis of results. It may be clearer for respondents, and for interpretation of results, to phrase items a-d as:

"This page told me about the (risk, benefits, etc.) of using this medicine in a way that I can understand."

It may not be necessary to ask both items e and f. Merck believes the difference between these two concepts is small, and it is therefore doubtful that respondents will give distinctly different answers to

these two items.

Consider adding items in this section that ask if the information in the brief summary encourages the respondent to talk with their doctor "about" and to "ask for" the advertised drug. Probe to determine which topic (what information) encourages that conversation.

Q. 7a-b

Merck suggests including either question 7a or 7b, but does not believe that both are required since the terms "unfavorable" and "negative" are synonymous to consumers.

Q. 7c-d

Merck believes that comparisons of Oncor to other prescription medicines that treat the same condition should make specific comparisons on the dimensions of risk and effectiveness.

Item 7f should be more specific, and ask:

"Based on this ad, what is the risk ***to you*** of treating your (insert condition) with Oncor. Would you say it is..."

Merck believes that any one of these questions (7f-h) is sufficient to measure perceived risk/safety. Respondents would be unlikely to say Oncor is both very risky in 7f and very safe in 7h.

If 7h remains in the questionnaire, a respondent's answer may lack meaning in the absence of a standard that addresses whether or not Oncor actually is safe or dangerous, since Oncor is a fictitious product.

Q. 8b-c

These questions ask for a subjective evaluation of statements made in the ad. A respondent's assessment of drug warnings may be influenced by other factors such as the severity of their condition and their symptoms. For example, debilitating asthma may make warnings of heart attack seem only slightly risky but for a respondent with mild asthma this warning may be interpreted as very risky and totally unacceptable. The current design does not allow for analysis of results by presence or severity of symptoms, or whether a respondent's condition infringes on his/her daily life.

Q. 9

Merck believes there should be a follow up question that asks respondents what information they looked for, where they looked, and

whether they were able to find information that answered their question(s). There may also be value in then asking those respondents questions about how that information was presented.

Q. 10f Merck believes this question may be too general. Respondents should first be asked how much they know about their condition. Then, separately, they should be queried about the medicines that treat that condition. Caregivers would be asked about the condition and medicines used by the person in their care.

Additional Considerations

Consumers' information needs, how they use print advertisements, and their assessments of the information in these ads may vary according to their opinions of the pharmaceutical industry, their opinions of the practice of DTC advertising, and their level of involvement with the ads. Accordingly, Merck suggests the following additional questions for consideration:

1) Does the respondent have a favorable or unfavorable opinion of the pharmaceutical industry?

2) Does the respondent have a favorable or unfavorable opinion of DTC advertising?

3) Has the respondent seen advertisements for prescription medicines they are currently taking?

4) Has the respondent asked for a specific prescription medicine as a result of seeing it in an advertisement?